REMARKS

This amendment is responsive to the Office Action mailed June 16, 2006. Claims 1-6, 9, 10, and 22-34 are pending. Claims 17-21 have been cancelled. Claims 7-8 and 11-16 have been withdrawn as directed to non-elected species; however, upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 C.F.R. § 1.141.

Claim 1 has been amended herein to obviate the statutory double patenting rejection. Support for the amendment is apparent throughout the specification and claims, *e.g.*, *see* pages 11-15 of Applicant's specification. Additional support is found in the Examiner's determination of and election of species set forth in the Office Action dated March 2, 2006. Applicant notes that the present double patenting rejection was caused the Examiner's refusal to enter the Rule 312 amendment at the end of prosecution of the parent case, wherein Applicant requested the rejoinder of the remaining dependent claims (which merely specified the particular strains of avirulent enteropathogens encompassed by the allowed main claim) by way of a Rule 312 amendment. The Examiner, however, refused to consider the amendment, making the filing of the present divisional necessary. The failure of the Examiner to acknowledge that the particular deposited strains are species of the genus "avirulent derivative of an enteropathogenic bacterium" caused the double patenting paradox, in that Claim 1 of US Pat. No. 6,866,847 and Claim 1 of the present application have been determined to be directed to separate inventions even though they are identically worded.

Response to issues presented under 35 U.S.C. §103

Curtiss in view of Peterson

Claims 1-6 and 23-24 are rejected under 35 U.S.C. §103(a) as unpatentable over Curtiss, III et al., *Veterinary Immunology and Immunopathology*, 54:365-372 (1996) (hereinafter "Curtiss I") in view of US Patent No. 4,449,968 issued to Peterson (hereinafter "Peterson"). Applicants traverse.

Applicants submit that the Examiner has not made a *prima facie* case of obviousness. MPEP §2143.03 states that "[t]o establish *prima facie* obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art." (emphasis added) Obviousness cannot be established using Applicants' own disclosure as a guide to merely selecting and reconstructing the claimed invention from elements scattered in the prior art:

"When the references are in the same field as that of the applicant's invention,

> knowledge thereof is presumed. However, the test of whether it would have been obvious to select specific teachings and combine them as did the applicant must still be met by *identification of some suggestion, teaching, or motivation in the prior art, arising from what the prior art would have taught a person of ordinary skill in the field of the invention.*" *In re Dance*, 160 F.3d 1339, 1348, 48 USPQ2d 1635, 1637 (Fed. Cir. 1998) (emphasis added).

In the Office Action, the Examiner states:

> "The avirulent S. typhimurium vaccine strain was administered as a coarse spray to newly hatched chicks and then administered in the drinking water to chicks 10 days of age or older." (Office Action, page 6.)

However, contrary to the Examiner's statement, the Curtiss publication describes the oral administration of avirulent *Salmonella typhimurium* vaccines to chickens. All the data and results discussed in the publication stem from oral administration of the live attenuated Δcya Δcrp *S. typhimurium* strain χ3985. For example, the Discussion states:

> "Based on studies to date, it appears that ***oral immunization*** of poultry with a live avirulent *Salmonella* will significantly contribute to the reduction in *Salmonella* infection and colonization of poultry and thus lessen the likelihood for *Salmonella* transmission through the food chain to humans." (See, Curtis, page 370) (emphasis added).

Any mention the Curtiss publication makes of spray administration of vaccine to newly hatched poultry is in the context of a transgenerational vaccination program beginning with oral vaccination of the parental generation:

> "Immunization of chicks destined to be breeders and then with a booster immunization at 16-18 weeks of age leads to ***maternal transfer*** of immunity to chicks ***which then*** can be immunized either orally or by coarse spray to display an enhanced immunity to prevent infection of visceral organs by and shedding of Salmonella." (Curtiss, page 365, Abract.) (emphasis added)
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> * * *
>
> "We anticipate that the best immunization regimen would be to ***vaccinate breeders*** with the live attenuated Δcya Δcrp *S. typhimurium* strain χ3985 ***followed by vaccination*** by coarse spray or in drinking water ***of the chicks from those breeders***. (Curtiss, page 370, in last paragraph.) (emphasis added).
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> * * *
>
> "[W]e anticipate that birds hatched from eggs from immunized breeders

> and then immunized should display a more robust immune response and thus have a performance advantage over chicks that have never been immunized." (Curtiss, page 371, last sentence before Acknowledgements)

Thus, the only mention of spray vaccination in Curtiss relates to possible methods of continuing *maternally-transferred* immunity to the next generation of chicks using spray or oral administration as a method of boosting. This regimen is speculative with respect to the immunization of the chicks, as is evident from the fact that the remarks of the Curtiss publication are prefaced with "we anticipate..." Moreover, as stated throughout the prosecution of this case and the parent case, no data on whole-body spray vaccination of chicks is presented in the Curtiss publication. From this, it is clear that the Curtiss reference amounts to no more than an invitation to conduct experiments in the area of maternal transfer of immunity, and no detailed guidance as to what success may be expected by whole-body spraying of hatchlings is presented.

Applicant points out, furthermore, that none of the references in Curtiss to a "coarse spray" specify a whole-body spray. It is not possible to derive whether the teaching of Curtiss relates to spray directed to the beak, or to the eye, or down the throat, or to the head, or to more or less of the whole body of chicks exposed to the coarse spray mentioned. Nor is there any speculation that would suggest the critical droplet size range for a spray that is recited in Applicant's claims.

Without any experimental data to demonstrate how a coarse spray as mentioned by Curtiss is applied, and without a demonstration of how whole-body spraying can effectively immunize newly hatched poultry, especially outside the context of maternal transfer of immunity, the Examiner cannot fairly contend that the present invention as claimed was placed in the hands of the public by the Curtiss reference.

The Peterson reference is directed to the spray administration of live ***virus*** vaccine to poultry for protection against ***respiratory*** diseases such as Newcastle's Disease and infections bronchitis. For example:

> "Thus, it is an object of the present invention to provide a poultry vaccination system which rapidly and reliably administers live **virus** vaccine to baby chicks, without having to individually handle each baby chick." (Column 2, lines 18-21 of the '968 patent, emphasis added.)
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> ***
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> "It is customary to vaccinate poultry that is raise for commercial

> purposes against various **respiratory diseases** such as Newcastle's Disease and infectious bronchitis." (Column 1, lines 10-13 of the '968 patent, emphasis added.)
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> ***
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> "The spray is directed in a downwardly inclined pattern so that the droplets are likely to make contact with the upper body portions of the chicks in the open top container, **particularly with the eyes of the chicks**." (Column 1, lines 53-56 of the '968 patent, emphasis added.)
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> ***
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> "The vaccine tens to be **introduced into the sinus and respiratory systems** of the chicks by **passing from the eyes of the chicks into the nasal passages**." (Column 2, lines 63-66 of the '968 patent, emphasis added.)

There is no teaching or suggestion in Peterson of a method of delivering a protein to a domestic bird via whole-body spray administration of a live avirulent derivative of an enteropathogenic bacterium transformed to express a desired protein, wherein the enteropathogenic bacterium is other than one that causes respiratory disease in birds.

Thus, the reference combination of Curtiss and Peterson does not provide any teaching at the time of Applicant's invention relating to the effectiveness of whole-body spray for delivery of a protein to poultry via a bacterial vector.

The combination of references relied on by the Examiner does not provide enough of a teaching to make it obvious to a person of ordinary skill in the art at the time of Applicant's invention that whole-body spray would be an effective way of delivering a protein to chicks using an avirulent enteropathogenic bacterial vector. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection of Claims 1-6 and 23-24 under 35 U.S.C. §103(a).

Curtiss in view of Peterson in further view of Curtiss '345

Claims 9-10 are rejected under 35 U.S.C. §103(a) as unpatentable over Curtiss, III et al., *Veterinary Immunology and Immunopathology*, 54:365-372 (1996) (hereinafter "Curtiss") in view of US Patent No. 4,449,968 issued to Peterson (hereinafter "Peterson") in further view of US Patent No. 5,672,345 (hereinafter "Curtiss '345") . Applicants traverse.

The deficiencies of the Curtiss and Peterson references have been discussed above and

Applicant's comments are applicable to this rejection as well. The addition of Curtiss '345, teaches the *asd* balanced-lethal strains, which Applicant has already stated were known in the art, *see,* page 11, line 20 through page 12, line 3. What Curtiss '345 does not teach, however, is *the effectiveness of whole-body spray for delivery of a protein to poultry via a bacterial vector.*

Once again, the combination of references relied on by the Examiner does not provide enough of a teaching to make it obvious to a person of ordinary skill in the art at the time of Applicant's invention that whole-body spray would be an effective way of delivering a protein to chicks using an avirulent enteropathogenic bacterial vector. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection of Claims 9-10 under 35 U.S.C. §103(a).

Response to issues present under 35 U.S.C. §101 – Statutory Double Patenting

Claims 1-6 and 22-33 are rejected under 35 U.S.C. §101 as claiming the same invention as that of claims 1-6 and 12-23 of the parent application, US Patent No. 6,866,847. Applicant has amended Claim 1 herein. Accordingly, the claims are no longer coextensive in scope with the claims of the '847 application. Reconsideration and removal of the rejection under 35 U.S.C. §101 is respectfully requested.

Additional comments

Applicant's remind the Examiner that, as noted by the Examiner in Paragraph 5 of this Office Action dated March 2, 2006:

> "Upon the allowance of a generic claim, **applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim** as provided by 37 CFR 1.141." (emphasis added)

Applicant directs the Examiner's attention to MPEP §806.04(d), which states:

> "Once a claim that is determined to be generic is allowed, **all of the claims drawn to species in addition to the elected species which include all the limitations of the generic claim will ordinarily be obviously allowable in view of the allowance of the generic claim,** since the additional species will depend thereon or otherwise include all of the limitations thereof." (emphasis added)

Once again, Applicant notes that Claim 1, which is generic to all the species set forth in the election requirement, **has already been patented** in the parent case. *See, e.g.*, US Patent No. 6,866,847.

Applicant notes that already patented Claim 1 is the only independent claim in the claim set, i.e., Claims 2-34 all ultimately depend from Claim 1, therefore fulfilling the requirement "depend from or otherwise require all the limitations of an allowable generic claims as provided by 37 CFR 1.141," therefore entitling the Applicant to examination of the additional species recited in the dependent claims, *as noted by the Examiner in Paragraph 5* of the Office Action. Moreover, as noted in MPEP §806.04(d), all of the claims drawn to species in addition to the elected species which include all the limitations of the generic claim **will ordinarily be obviously allowable in view of the allowance of the generic claim**, since the additional species will depend thereon or otherwise include all of the limitations thereof.

Conclusion

Every effort has been made to advance the case to allowance, to particularly and distinctly define the subject matter of the invention, and to distinguish the invention over the prior art of record. In view of the foregoing remarks, reconsideration and allowance of the claims are respectfully requested.

Respectfully submitted,

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December 18, 2006
date

Nasim G. Memon